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PATENT APPLICATION

of

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for

METHOD AND DEVICE FOR THE ENDOSCOPIC APPLICATION OF SELF-CLOSING MEDICAL CLIPS

Field of the Invention

The present invention relates to a method and device for endoscopic application of self-closing medical clips, especially for stopping internal hemorrhages, in which a catheter tube with its distal end is placed in the body of the living being to be treated.

Background of the Invention

Different processes using flexible endoscopes are known for stopping internal hemorrhages, for example, in the upper or lower gastrointestinal tract from varicose hemorrhages, post-polypectomy hemorrhages or ulcerative hemorrhages. Examples include coagulation, sclerosing, ligature, or application of self-closing clips. All the known processes are subject to disadvantages in various respects, whether the therapeutic success is not satisfactory or use is complex or very expensive. Recently, as the preferred process, the clip procedure has become established as being relatively favorable, that is, subject to few disadvantages. Further applications of these clips can be found in the area of attaching markers for identification of diagnostic or x-ray sections and surgical treatment procedures, for example, removal of polyps in the gastrointestinal tract.

In the clip procedure, a metallic clip is pushed out of the distal end of a catheter tube, opened and placed at the hemorrhage site such that it forms a clamp which clamps off the hemorrhage. U.S. Patent No. 5,174,276 shows a device designed for implementing this clip procedure.

When the clip procedure is being carried out, in many cases several clips are needed to stop the bleeding. In the known clip procedure, this disadvantageously leads to delays in the course of the treatment because the applicator device must be removed from the body each time for re-seating of clips, provided with another clip, reinserted into the body with the catheter tube and placed at the treatment site. This procedure leads not only to a prolongation of the course of treatment, which can result in serious danger to the patient in a case of heavy bleeding, but also entails the danger of faulty placement.

Summary of the Invention

An object of the present invention is to provide a process which permits multiple placement of hemostatic clips in immediate succession, without the need to provide the endoscopic device with another clip outside of the body for each application.

This object is basically achieved by a process according to the present invention, where the catheter tube itself is used as a magazine which is loaded with several clips before implementing the pertinent treatment. Multiple application of hemostatic clips in immediate succession is made possible without the endoscopic device needing to be removed from the body after each clip application. Rather, the frontmost clip can be pushed out of the distal end of the catheter tube, opened by an actuating element acting on it, and placed on the hemorrhage site to be treated. The actuating element is detached from the clip so that it is released and its self-closing legs effect the hemostatic clamping, after which the actuating element is functionally linked to the clip which follows in sequence in the catheter tube, so that if necessary the next clip can be applied without delay. Preferably the clips are already loaded by the manufacturer. In particular, in the case of special applications it is also possible to magazine the clips on site, that is to say, at the site of the procedure. Preferably, flexible spiral tubes resistant to tension and compression, but also tube-like flexible application bodies can be used as the catheter tube.

Another object of the present invention is to provide a device for implementing the process. In the device of the present invention, a control part converts the actuation force of the actuating element, which can be controlled by the operator of the device into the opening motion of the legs of the clip. The control part is located on the distal end of a sleeve-like receiving part associated with the respective clip. The clip is shaped on its legs adjacent to each other such that when the clip is inserted into the receiving part, an opening motion of the free leg ends takes place by the kink of the two legs which forms an arch striking the control part. If, after opening the clip, the kink on the legs is disengaged from the sleeve-like receiving part by the actuating element, the legs of the clip are released again in order to be closed by their own elasticity at the application site. This closing process can be further promoted by deformation at the kink of the clip effected by the sleeve-like receiving part and, in certain configurations, can also be replaced exclusively by the indicated deformation.

The actuating element can be a pulling element, and the control part can be a beveled control surface located on the end edge of the sleeve-like receiving part. The opening and subsequent closing of the legs of the clip which is to be applied are effected by pulling the clip into its receiving part. The opening motion takes place by the kink of the legs striking the control surface. Subsequently pulling the kinks through the receiving part effects the clip legs being released for the closing motion as soon as the kinks of the legs have run through the sleeve-shaped receiving part. The beveled control surface can also be formed by the curved control surface's running convexly or concavely.

The pulling element can be a pull cable. To connect the pull cable to the clip, on the clip back end crosspiece connecting the legs, each clip can have two adjacent through holes. The cable extends through those holes in a loop, such that it extends in an advancing strand to the clip and back from the latter back in a retreating strand to the operator means. The section of the end crosspiece of the clip located between the through holes is made as a predetermined breaking point which can be broken by the pulling force of the pull cable acting by the loop. The pull cable can then be easily detached from the clip after completion of the actuating process.

The procedures of pulling the clip into the receiving part and of detaching the pull cable from the applied clip are especially safe, i.e., without the danger of the clip's changing location by the force applied by the pull cable at the predetermined breaking point. On the distal end of the catheter tube, a blocking element permits the passage of the sleeve-like receiving part with the respective clip only in the exit direction forward, and supports the sleeve-like receiving part against the motion effected by the pulling force of the pull cable.

In an especially advantageous manner, these embodiments can be further configured such that in the catheter tube there are several clips with the respective sleeve-like receiving part in succession. The pull cable with the advancing strand and with the retreating strand is guided in each case through one or the other through hole of the end crosspieces of all clips.

With such a structure of the device, several clips can be applied in direct succession. After the pull cable is pulled off, the applied clip the device is immediately functionally linked to the respective following clip by pulling on the pull cable. This action takes place by the pull cable on the end crosspiece of the following clip automatically forming a loop assembly. Thus, without any other measures being necessary, the device is immediately prepared for application of the following clip.

Other objects, advantages and salient features of the present invention will become apparent from the following detailed description, which, taken in conjunction with the annexed drawings, discloses a preferred embodiment of the present invention.

Brief Description of the Drawings

Referring to the drawings which form a part of this disclosure:

FIG. 1 is a schematically simplified, side elevational view in section of only the distal end section of the catheter tube as a component of the device according to one embodiment of the present invention, with this section being shown on an enlarged scale compared to the natural size;

FIG. 2 is a perspective view of a self-closing medical clip drawn on a still larger scale, for use in the device of the present invention;

FIG. 2a is a further enlarged perspective view of only the end crosspiece of the clip of FIG. 2, which crosspiece is provided with a predetermined breaking point;

FIGS. 3 and 4 are schematic, side elevational views of the device of FIG. 1 illustrating the movements and forces for opening of the clip;

FIGS. 5 to 13 are schematic, side elevational views of only the distal (front) end of the catheter tube of FIG. 1, with the clip having emerged and with the respective sleeve-like receiving part, successive operating states being shown as the opening and closing cycle of the clip proceeds, and

FIG. 14 is a highly enlarged perspective view of a blocking element designed as a collet for the distal end of the catheter tube of FIG. 1.

Detailed Description of the Invention

FIG. 1 shows the distal end section of the catheter tube 1 as a component of an exemplary embodiment of the device of the present invention. The catheter tube 1 extends through the associated working space of a flexible endoscope which can be of conventional design in medical technology and which contains at least one other inner working space for endoscope optics including illumination and/or for other purposes (for example, suction). The proximal end (not shown) of the catheter tube 1 is functionally connected to the manipulation and operator means located on that end of the endoscope. The outside diameter of the catheter tube 1 is 2.7 mm corresponding to the clearance of the working spaces in flexible endoscopes.

The device of the present invention is suited for application of self-closing medical clips 3 of a design as can be seen most clearly from FIGS. 2 to 4. The clip 3 is formed from a material such as high quality steel customarily used for medical purposes, and has two legs 5 which, without

crossing one another, are adjacent to each other and are bent toward each other on the clip free leg end 7. On the end opposite the leg end 7, the legs 5 are connected to each other by an end crosspiece 9 having through two through holes 11 adjacent to each other. Offset from and between the end crosspiece 9 and the free leg end 7, each leg 5 has a first kink 13 arched to the outside and closer to end crosspiece 9 than to the leg end 7, and a second kink 15 arched to the inside and closer to the leg end 7 than the first kink. The second kinks is together form a support point for the mutual contact of the legs 5. From the second kink 15, the remaining sections of the legs 5 extend more or less parallel to each other to the free leg end 7 when the clip 3 is in the closed state, as is shown in FIGS. 2 and 3, i.e., the initial state of the clip 3.

The functional diagrams of FIGS. 3 and 4 using the sleeve 17 and a counter bearing 19 show the forces which effect opening of the legs 5 under the action of a pulling force applied by a pull cable 21 to the clip 3 corresponding to the action arrow 23 in FIG. 4. Upon contact with the beveled control surface 25 on the end edge of the sleeve 17, a force directed inwardly (see arrow 27) acts on each first kink 13, the legs 5 being extended (see arrows 29 in FIG. 3) with the second kinks 15 for mutual support. Due to the pulling force which continues to act (arrow 23), the legs 5 at the support point of the second kinks 15 seesaw on each other, which results in the opening-pivoting of the legs 5 according to arrows 31 (FIG. 4).

FIG. 1 shows the catheter tube 1 with several clips 3 in succession, each forming a unit with a sleeve-like receiving part 33. In its operation, the receiving part 33 corresponds in the interaction of its front control surface 25 with the respective clip 3 of the sleeve 17, as shown in FIGS. 3 and 4 to illustrate the forces acting on the clip 3. In FIG. 1, two clips 3 with the respective receiving parts 33 are accommodated in the catheter tube 1. But in practical application, the catheter tube 1 can be provided as a magazine for 2 to 10 clips, preferably for 2 to 5 clips or more. As FIG. 1 shows, the units including the clip 3 and receiving part 33 can be moved in the catheter tube 1 by a sliding tube 35 with a front end edge 37 forming a plunger for contact with the adjacent receiving part 33 and with a proximal end which can be manipulated as part of the actuating means from the operator means on the outer actuating end of the endoscope.

As is likewise apparent from FIG. 1 in conjunction with FIGS. 2 to 4, the pull cable 21 extends in the catheter tube 1 as the actuating element in two strands 24 through the through holes 11 (see FIG. 2) of each clip 3. On the frontmost clip 3, a loop 39 is formed on the end crosspiece 9 (FIG. 1). The loop 39 is also shown in the schematics of FIGS. 3 and 4. The strands 24 of the pull cable 21 are routed in the catheter tube 1 through the sliding tube 35 as the actuating element as far as the operator means on the outer end of the endoscope.

When the device is being used, the clips 3 are arranged in succession in the catheter tube 1 with the associated receiving parts 33, and are advanced by the sliding tube 35 until the receiving part 33 of the frontmost clip 3 has left the catheter tube 1, more precisely, has passed through a blocking element 41 mounted on the distal end of the catheter tube 1. After passing through the blocking element 41, this receiving part 33 with the respective clip 3 is in the position shown in FIG. 5.

FIG. 14 shows the blocking element 41 separately. The blocking element 41 is a tube piece 43 which lengthens the catheter tube 1 and which has longitudinal slots 44 in its end part so that jaws 45 are formed as a kind of collet and under normal conditions reduce the passage clearance of the tube piece 43. The passage of the receiving part 33 in a slightly elastic way spreads the jaws 45 which assume the blocking position shown in FIGS. 5 to 13 after emergence of the receiving part 33, so that the receiving part 33, having emerged, is supported against moving backward. A central, projecting shoulder 47 of the receiving part 33 engages as a centering piece between the jaws 45 of the blocking element 41.

FIGS. 5 to 13 illustrate in a highly simplified schematic the progression of the opening and closing cycle of the clip 3 with the receiving part 33, which clip is to be applied and which has been pushed out of the blocking element 41. This entire cycle is effected by pulling on the pull cable 21. FIG. 5 shows the clip 3 activated for application with the sleeve-like receiving part 33 having been pushed out of the blocking element 41, the clip 3 not yet having been pulled into the receiving part 33 by the pull cable 21 to the extent that the first kinks 13 of the legs 5 would strike the beveled

control surface 25 of the receiving part 33. The beveled control surface 25 corresponds to the oblique surface 25 on the sleeve 17 already discussed using the operating diagrams 3 and 4.

FIGS. 6 to 9 show the operating states which arise in succession by pulling the pull cable 21. The legs 5 of the clip are progressively opened by the first kinks 13 striking the control surface 25 until the state of complete opening is reached as shown in FIG. 9.

FIGS. 10 to 13 shows the closing cycle which results as the pull cable 21 continues to be pulled. The legs 5 close due to the inherent elasticity of the clip 3 and/or its deformation being completely released, as soon as the clip 3 has been pulled correspondingly far through the receiving part 33 such that an opening force is no longer being applied by the first kinks 13. This state is reached when the clip 3 is being pulled further beyond the position shown in FIG. 13 through the receiving part 33. After application which has taken place by the closing of the clip 3 at the hemorrhage site to be treated to completely release the applied clip 3, the pull cable 21 continues to be pulled to detach the pull cable from the applied clip. The applied clip is supported with its end having the end crosspiece 9 (FIG. 2) on the leg end 7 of the clip 3 following next in the catheter tube 1 or on the end edge 37 of the sliding tube 35. This detaching takes place by pulling harder on the pull cable 1 to apply a detachment force. Preferably, in one alternative embodiment, instead of the respective clip being supported on a following clip in the magazine when the pull cable 21 is pulled off, support is accomplished preferably exclusively by the sleeve-like receiving part 33. For this support, the clip at least partially transversely to its opening direction has blade-like widenings (not shown) on the legs 5 between the leg end 7 and the assignable second kink 15 and oppositely adjacent to the second kink, which widenings permit an interlocking option of the clip 3 in the sleeve-like receiving part 33 so that the necessary opposing holding force is thus formed for pulling off the pull cable 21 by the predetermined breaking point 51. This blade-like widening adjoins flanking on either side of the respective leg 5 of the clip 3.

As can be clearly seen in FIG. 2a, for this purpose, in the end crosspiece 9 connecting the legs 5 of the clip 3 on the back end, between the through holes 11, a predetermined breaking point 51 is dimensioned such that the loop 39 of the pull cable 21 effects tearing through of the

predetermined breaking point 51 when a predetermined pulling force is applied, which in practical embodiments is approximately 40 N. The applied clip 3 with the associated receiving part 33 thus remains at the treatment site, while after the process of tearing off, the pull cable 21 as a loop 39 automatically adjoins the end crosspiece 9 of the following clip which can be advanced by pushing forward by the sliding tube 35 for the immediately following application process.

The predetermined breaking point 51 can be made as shown in FIG. 2. It is also possible to make the predetermined breaking point from a different material which can be easily torn and which is different from that remaining material of the end crosspiece 9. Furthermore, it is also possible to make the end crosspiece 9 uniform in its material to form the predetermined breaking point and the end crosspiece 9 tears if a definable maximum force is exceeded with the pull cable 21. The collet shown in FIG. 14 is fixed with its tube piece 43 as shown in FIG. 1 on the inside circumference of the free end of the catheter tube 1. It is also possible for the tube piece 43 to enclose the respective free end of the catheter tube 1 and to be held seated there by an adhesive connection and/or force fit.

As is to be seen, the entire application process can be carried out by pulling on the pull cable which is provided as the actuation element and which can be a fine steel cable. For the opening of the respectively activated clip 3 by pulling into the receiving part 33, the release of the pivoting motion of the legs 5 by pulling through the receiving part 33, and the detachment of the pull cable 21 by tearing the predetermined breaking point 51, the pull cable is moved automatically into contact with the end crosspiece 9 of the following clip 3 in the catheter tube 1. The device is then again immediately ready for the following application process. With the device of the present invention, it is possible to stop hemorrhages. The clip can also be used for marking purposes, for example, in the field of diagnostics. Also, surgical procedures can be carried out in which the clip is used as a surgical instrument, for example, for removing polyps in the gastrointestinal tract or the like.

While one embodiment has been chosen to illustrate the invention, it will be understood by those skilled in the art that various changes and modifications can be made therein without departing from the scope of the invention as defined in the appended claims.